K070936

Section 5: 510(k) Summary

JUL 16 2007

1. Preparation Date: March 30, 2007

2. Submitted by:

Welmed Inc.
691 Lake Street
Grayslake, IL 60030

Contact Person/Prepared by:

Darren Reeves
Management Representative
Phone (866) 393-4954
Fax (866) 393-4954
E-mail: dpdist@bww.com

3. Device Identification:

Trade Name: Welmed Hypodermic Syringe (various sizes)
Common Name: Syringes, Hypodermic
Classification Name: Piston Syringe (21 CFR 880.5860; Product Code FMF)

4. Predicate Device: Merit Medical Syringe (K024052)

5. Device Description:

The Welmed, Inc. Syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male Luer Lock connector (nozzle) for attaching the female Luer connector (hub) of a hypodermic single lumen needle, or for attaching other devices with a female Luer.

6. Intended Use:

The intended use of the Welmed, Inc. piston syringe is to inject fluids into or withdraw fluids from the body.

7. Statement to conform to ISO 7886-1; 1993

Welmed Inc. has established that its family of syringes corm to the FDA-recognized consensus standard, ISO 7886-1:1993, *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use*. Data supporting conformance with the standard is available from Welmed

8. Conclusion – Based on conformance with the recommended standard, Welmed syringes are safe and effective for the intended use.

9. Similarities/ Differences of the proposed device when compared to the predicate:

9.1.1 Intended Use
The Merit Medical syringes are intended to inject fluids into, or withdraw fluids from, the body. As such, the Intended Uses of the predicate and Welmed syringes are equivalent.

9.1.2 Materials
Materials used in the manufacture of Welmed syringes are typically used in the manufacture of general-purpose syringes, including the predicate device.

9.1.3 Design
The design of the Welmed syringe is typical for syringes, including that of the predicate.

9.1.4 Operational Principles
The Welmed syringe is manually operated by advancing and withdrawing the plunger in the barrel. The operating principles are identical for all manual syringes, including the predicate.

9.1.5 Technology
The same fundamental technology is used in the design of the Welmed syringes as is employed in the design of all manual syringes, including the predicate.

9.1.6 Safety and Performance
Welmed has provided a statement that its syringes conform to the requirements of IS0 7886-1 :I 993, an FDA- recognized consensus standard. This statement and the data that has been collected to support conformance has been used to demonstrate safety and performance in lieu of demonstrating substantial equivalence with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2007

Welmed, Incorporated
C/O Mr. Darren Reeves
Management Representative
DP Distribution and Consulting, LLC
15637 Fox Cove Circle
Moseley, Virginia 23120

Re: K070936
Trade/Device Name: Welmed Hypodermic Syringes (1,3,5,10,20,30 and 60 ml)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 23, 2007
Received: May 29, 2007

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

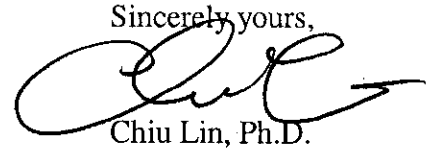
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070936

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use

510(k) Number (if known): __K070936____

Device Name: _____Welmed Hypodermic Syringes_____

Indications for Use:

The intended use of the Welmed, Inc. piston syringes is to inject fluids into or withdraw fluids from the body.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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